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Professional Implications of the Expansion of Retail-Based Clinics into Community Pharmacies

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ABSTRACT

Objective: To describe challenges and opportunities associated with the emergence of retail-based health clinics in community pharmacies.

Summary: Retail-based clinics have emerged as a convenient, low cost treatment option for many patients. These clinics, which are staffed by physicians' assistants or nurse practitioners, often are located directly within community pharmacies offering rapid diagnosis and treatment for a limited number of health problems. With plans for significant expansion, these clinics offer the profession of pharmacy with a number of challenges. Particularly, allocating space in community pharmacies for retail-based clinics could place pharmacists at a disadvantage to other providers as they pursue ancillary health care activities. These clinics also represent an opportunity for pharmacists to position themselves as a legitimized health care provider who is reimbursed for the consultative services they perform. Because most retail-based clinic conditions are easily diagnosed and have well established treatment protocols, pharmacists would be well positioned to provide these services under collaborative practice arrangements. This could ultimately provide the infrastructure necessary to offer other types of patient services, including Medication Therapy Management (MTM).

Conclusion: As retail-based clinics continue to proliferate, pharmacy should carefully consider surrendering space in community pharmacies to other health care practitioners. Retail-based clinics present pharmacists with an opportunity to provide many of the additional health care services we have so vigorously argued for. Failure to respond to

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the acute care needs of patients today may present pharmacists with a significant barrier as they continue to expand into direct patient care activities.

Retail pharmacists often are the most readily accessible health care member within their community. Although the majority of a pharmacist's time is spent on the dispensation of medications[1], retail pharmacists frequently are called on to diagnose and suggest treatment for a variety of minor health conditions. Most community pharmacies perform these services without reimbursement. While payment for these consultations has not been required for retail pharmacies to be profitable, revenue generated solely from dispensing medications would likely have declined over the past decade had the number of medications dispensed in pharmacies not increased. Two trends that raise further concerns about the profitability of retail pharmacies are smaller dispensing fees for prescriptions[2] and greater pharmacist salaries[3]. Additionally, pricing changes such as those proposed in state Medicaid programs have the potential to significantly diminish revenue derived directly from dispensing medications, particularly generics[4].

At the same time, the role of a pharmacist has slowly evolved beyond the dispensation of medication. Pharmacists now perform a number of additional services in community pharmacies including immunizations[5-7], disease management programs[8-11], medication therapy management services (MTMS)[12-14], and diagnostic screening services[15-17]. The adoption of these additional services reflects not only a greater need by patients for the expertise of a pharmacist, but also may represent a need by pharmacies to seek additional sources of revenue to remain profitable. However, recent research suggests that pharmacists have been slow to adopt additional services into their practices[18]. This comes in spite of greater automation of dispensing activities, extended

training requirements for student pharmacists associated with the adoption of the Pharm.D. program, and a desire by pharmacists to perform more clinical services[1].

Although pharmacists have been slow to adopt additional services into their retail practices, there is a movement in community pharmacies toward the provision of acute care services by mid-level practitioners. The emergence of retail-based health clinics in community pharmacies offers a unique set of opportunities and challenges for the profession of pharmacy as it seeks legitimacy in expanding its role as a health care provider. Allocating additional space in community pharmacies for retail-based health clinics could place pharmacists at a disadvantage to other health care providers as they pursue ancillary health care activities. The professional response to this trend could help provide the impetus to expand pharmacy practice beyond drug distribution to include a broader range of clinical services and patient care opportunities in the community setting.

Retail-Based Clinics in Community Pharmacies

In many different retail markets around the U.S., companies have set up retail-based clinics within pharmacies to rapidly diagnose and treat a limited number of health problems. The first retail-based clinics were opened in Minnesota as QuickMedx in 2000, later becoming Minute Clinic in 2002. There are now at least 12 different companies operating retail-based clinics in more than 150 different locations across 21 states [19]. It is estimated that there will be a rapid increase in the presence of retail-based clinics over the next several years with MinuteClinic® planning to open 300 clinics by the end of 2006 and Take Care Health Systems® planning to open 1400 clinics by the end of 2008. Given their rise in popularity, and considering the recent acquisition of Minute

Clinic by CVS, retail-based health clinics are likely to have a major presence in the future of community pharmacies.

Retail-based health clinics offer many acute health services at costs which are lower than those in traditional physician's offices. These clinics keep administrative costs to a minimum by operating on a fee-for-service model whereby patients pay strictly out-of-pocket for services rendered. This may or may not remain an advantage as health insurers recognize the benefit of these clinics and begin paying for services provided in them. Retail-based clinics also minimize expenses by employing mid-level practitioners (nurse practitioners and physician's assistants) whose salaries tend to be lower than physicians. Lower prices make retail based clinics an attractive option to patients who are more price-sensitive to health care treatments. Patient groups who may be more sensitive to the price of health care include the more than 40 million uninsured Americans.[20] They also include individuals who have signed on to consumer directed health plans, such as health savings accounts (HSAs), which have risen in popularity in recent years.[21] By combining tax-advantaged savings accounts with high-deductible insurance, these HSAs provide patients with incentives to lower health care spending.

In addition to price advantages, retail-based clinics also are likely to be viewed as a convenient treatment option. They tend to be open evenings and weekends, have minimal wait times to be seen, and are conveniently located within the pharmacy for any prescription needs. A recent internet survey of 2245 U.S. adults suggested that many adults think of retail based clinics as a convenient and affordable alternative to traditional health care sttings[22]. Of the 7% of respondents who had ever used a retail-based clinic before, the percent of respondents indicating they were somewhat to very satisfied was

92% for convenience, 89% for quality of care, 88% for qualifications of staff, and 80% for cost. Among respondents who had never used a retail-based clinic, 41% indicated that they would be somewhat to very likely to used such as clinic for medical services in the future.

Pharmacists Participation in Retail-Based Clinics

The introduction of mid-level practitioners into the retail pharmacy setting might be viewed as a setback to the greater role pharmacists have taken as health care providers. Given all of the in-roads that pharmacy has made positioning itself to provide direct patient care, one might wonder why additional pharmacy space would be used for retail-based clinical services provided by other health care practitioners. The spread of retail-based health clinics may, therefore, present the profession of pharmacy with a significant challenge as it begins to take on more patient responsibility. Allocating space for acute health care services provided by other practitioners could lead to an inability by pharmacists to provide MTM and other direct patient care services in the future. Pharmacy should consider using these clinics to position themselves as another health care provider who is reimbursed for the consultative services they perform.

The majority of services provided in retail-based health clinics tend to be for acute conditions (See Table 1). This differs from the chronic conditions such as osteoporosis, diabetes, hyperlipidemia, and asthma that pharmacy has focused on to date. These services tend to have easily identifiable diagnostic symptoms or are identified easily with minimally invasive laboratory tests, require minimal physical examination, and have well established treatment protocols. One can argue that with additional training, pharmacists may be well positioned to provide these services if desired. This

training could be incorporated into the basic Pharm.D. curriculum through acute care courses which would focus on the diagnosis of acute conditions, diagnostic screening, and physical examination procedures. Beyond this, consideration should be given to expanding community pharmacy residencies to include acute care training with the ultimate goal of broadening pharmacists' scope of practice to include more diagnostic and treatment responsibilities. Finally, pharmacy should pursue the development of collaborative practice arrangements to care for patients in retail-based pharmacy clinics either under a pre-approved protocol or as part of a multi-disciplinary team.

A broader scope of practice may not be viewed favorably by all practitioners. For example, a recent position paper by the American Colleges of Physicians (ACP) and American Society of Internal Medicine (ASIM) states that although they support pharmacist-physician collaborative practice arrangements, agreements should be limited to pharmacist involvement in patient education and hospital rounds.[23] They further stated that the physician should have sole responsibility for diagnosis of a patient's condition and prescriptive rights.[23] Given this stance, consideration should be given to how broadening prescriptive authority may affect the relationship between pharmacists and other providers.

Regardless of potential conflicts with other health care providers, there is a trend toward pharmacists taking on more prescriptive and diagnostic responsibilities. Many states have expanded prescriptive authority for pharmacists under certain criteria. For example, Florida pharmacists have the ability to prescribe prescription antihistamines and prescription topical anti-infectives.[24] Additionally, some states also now allow pharmacists to provide emergency contaception directly to patients without a

prescription.[25] There has even been discussion about allowing pharmacists to provide low dose statin therapies to patients without a prescription.[26, 27] These actions, in addition to the withdrawal of pseudoephedrine from open access over-the-counter, represent a desire for greater access to medications given only through the discretion of a pharmacist.

Some states have taken an even more aggressive stance in allowing pharmacists to prescribe medications and perform physical assessments. For example, "Pharmacist Clinicians" in New Mexico are given equivalent prescribing authority to a Physician's Assistant after having undergone 60 hours of physical assessment training and a defined period of physician supervised physical assessment experience.[28] Similarly, North Carolina allows pharmacists to become certified as "Clinical Pharmacist Practitioners" (CPPs)[29] CPPs are approved to provide drug therapy management, under the supervision of a licensed physician and to order, change, and substitute medication therapies and order diagnostic tests. Given their prescriptive authority, clinical pharmacists such as those in New Mexico and North Carolina would be uniquely positioned to provide acute care services such as those performed in retail-based clinics.

Professional Implications for Pharmacy

The passage of the Medicare Modernization Act of 2003 heralded the arrival of MTM, an activity long advocated for by the pharmacy profession as necessary for optimizing patient outcomes associated with drug therapy. Many see this as the future of our profession. However, barriers still exist to the widespread and successful implementation of MTM. Recent research still suggests that patients are unsure of pharmacists' clinical and professional role[30,31]. Moreover, pharmacies are not designed with direct patient care services in mind. Many community pharmacies have limited

space and require additional controls to insure patient privacy. Consultation windows with dividers may not be sufficient to curb outside distractions and do not provide an adequate environment for physical assessment.

The expansion of pharmacists into retail-based clinics could help dissolve some of the current barriers prohibiting pharmacists from taking on a broader clinical role. The move would help provide legitimacy to the relationship between a patient and pharmacist. It would also raise patient awareness that pharmacists are taking on additional patient care responsibilities. Additionally, retail-based clinics provide the infrastructure necessary to offer other types of patient services in a more appropriate setting. Staffing retail-based clinics with pharmacists, instead of other mid-level practitioners, seems a logical step in establishing the pharmacist as a legitimate health care provider who should be reimbursed for direct patient care.

It could be argued that taking on an advanced acute care role leads pharmacists astray from their responsibility as a medication expert. However, it should be realized that pharmacists provide many of the acute care services listed in Table 1 on an informal basis every day. With a minimal amount of advanced training, and in collaboration with physicians, pharmacists with a desire to perform additional health care services such as those provided in retail-based clinics should be allowed to do so. Moving into a more clinically oriented role will require some discussion about how to modify our pharmacy school curriculums and post-graduate residency programs. In addition, regulatory changes that allow for collaborative practice arrangements must be considered. As highlighted, there are already numerous examples of state specific collaborative practice arrangements from which to work from. Additional research should consider how

existing regulations might be expanded to include the acute care services presently offered in retail-based pharmacy clinics.

As retail-based clinics continue to proliferate, the profession of pharmacy should carefully consider how willing we are to surrender space in community pharmacies to other health care practitioners. Retail-based clinics present community pharmacists with a unique opportunity to provide many of the additional health care services we have so vigorously argued for. Failure by pharmacy to respond to the acute care needs of patients today may present the profession with a significant hurdle as it continues to expand into direct patient care activities.

REFERENCES

1. Schommer JC, Pedersen CA, Gaither CA, Doucette WR, Kreling DH, Mott DA. Pharmacists' desired and actual time in work activities: evidence from the 2004 National Pharmacits Workforce Study. *Journal of the American Pharmacists Association.* 2006;46(3):340-347.
2. Pracht EE, Moore WJ. Interest groups and state Medicaid drug programs. *Journal of Health Politics, Policy, and Law.* 2003;28(1):9-39.
3. Cardinale V. Flying High: Are rising wages and generous benefits enough to attract pharmacists and keep them from roaming? *Drug Topics*; 2005.
4. Federal Deficit Reduction Act, House Report 109-362, H.R. 4241, S. 1932; 2005.
5. Weitzel K, Goode J. Implementation of a pharmacy-based immunization program in a supermarket chain. *Journal of the American Pharmaceutical Association.* 2000;40(2):252-256.
6. Rosenbluth S, Madhavan S, Borker R, Maine L. Pharmacy immunization partnerships: a rural model. *Journal of the American Pharmaceutical Association.* 2001;41(1):100-107.
7. Ernst ME, Chalstrom CV, Currie JD, Sorofman B. Implementation of a community pharmacy-based influenza vaccination program. *Journal of the American Pharmaceutical Association.* 1997;37(5):570-580.
8. Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project ImPACT: hyperlipidemia.[see comment]. *Journal of the American Pharmaceutical Association.* Mar-Apr 2000;40(2):157-165.
9. Kennedy DT, Giles JT, Chang ZG, Small RE, Edwards JH. Results of a smoking cessation clinic in community pharmacy practice.[see comment]. *Journal of the American Pharmaceutical Association.* Jan-Feb 2002;42(1):51-56.
10. Knowlton CH, Thomas OV, Williamson A, et al. Establishing community pharmacy-based anticoagulation education and monitoring programs. *Journal of the American Pharmaceutical Association.* May-Jun 1999;39(3):368-374.
11. Berringer R, Shibley MC, Cary CC, Pugh CB, Powers PA, Rafi JA. Outcomes of a community pharmacy-based diabetes monitoring program.[see comment]. *Journal of the American Pharmaceutical Association.* Nov-Dec 1999;39(6):791-797.
12. Ernst ME, Doucette WR, Dedhiya SD, et al. Use of point-of-service health status assessments by community pharmacists to identify and resolve drug-related problems in patients with musculoskeletal disorders. *Pharmacotherapy.* Aug 2001;21(8):988-997.
13. Kassam R, Farris KB, Burback L, Volume CI, Cox CE, Cave A. Pharmaceutical care research and education project: pharmacists' interventions. *Journal of the American Pharmaceutical Association.* May-Jun 2001;41(3):401-410.
14. Shibley MC, Pugh CB. Implementation of pharmaceutical care services for patients with hyperlipidemias by independent community pharmacy practitioners. *Annals of Pharmacotherapy.* Jun 1997;31(6):713-719.
15. Elliott ME, Meek PD, Kanous NL, et al. Osteoporosis screening by community pharmacists: use of National Osteoporosis Foundation resources. *Journal of the*

American Pharmaceutical Association. Jan-Feb 2002;42(1):101-110; quiz 110-101.

16. Simpson SH, Johnson JA, Tsuyuki RT. Economic impact of community pharmacist intervention in cholesterol risk management: an evaluation of the study of cardiovascular risk intervention by pharmacists. *Pharmacotherapy.* May 2001;21(5):627-635.
17. Tice B, Phillips CR. Implementation and evaluation of a lipid screening program in a large chain pharmacy. *Journal of the American Pharmaceutical Association.* May-Jun 2002;42(3):413-419.
18. Doucette WR, Kreling DH, Schommer JC, Gaither CA, Mott DA, Pedersen CA. Evaluation of community pharmacy service mix: evidence from the 2004 National Pharmacist Workforce Study. *Journal of the American Pharmacists Association.* 2006;46(3):348-355.
19. Sullivan D. Retail health clinics are rolling your way. *Family Practice Management.* 2006;13(5):65-72.
20. *Institute of Medicine. Coverage Matters: Insurance and Health Care*. Washington D.C.: National Academy Press; 2001.
21. Feldman R, Parente ST, Abraham J, Christianson JB, Taylor R. Health savings accounts: early estimates of national take-up. *Health Affairs.* 2005;24(6):1582-1591.
22. Many agree on potential benefits of onsite clinics in major retail stores that can provide basic medical services, yet large numbers are skeptical. Accessed July 25, 2006.
23. American College of Physicians-American Society of Internal Medicine. Pharmacist scope of practice. *Annals of Internal Medicine.* 2002;136(1):79-85.
24. Florida Statutes: Pharmacy, 465.186. *465.186.*
25. Monastersky N, Landau SC. Future of emergency contraception lies in pharmacists' hands. *Journal of the American Pharmacists Association.* 2006;46(1):84-88.
26. Cohen JP, Paquette C, Cairns CP. Switching prescription drugs to over the counter. *British Medical Journal.* 2005;330(1):39-41.
27. Strom BL. Statins and over-the-counter availability. *New England Journal of Medicine.* 2005;352(14):1403-1405.
28. New Mexico Occupational and Professional Licensing: Pharmacists, Pharmacist Clinician. Title 16, Chapter 19, Part 4.17.
29. North Carolina Administrative Code: Clinical Pharmacist Practitioner, NCAC 46.3101.

TABLE 1: Minute Clinic(www.minuteclinic.com) Treatment Menu and Price Listing

	Condition	Price
Common Illnesses	Allergies (ages 6+), Bronchitis (ages 10-64), Ear Infections, Pink Eye and Styes, & Strep Throat	$49
	Bladder Infections (females ages 12-64) & Strep Throat	$59
Skin Conditions	Athletes Foot, Cold Sores, Deer Tick Bite, Impetigo, Minor Burns & Rashes, Minor Skin Infection, Poison Ivy, Ringworm, & Swimmer's Itch	$49
	Wart Removal	$59
Vaccines	Flu & Pneumonia	$30
	Tetanus/Diptheria	$45
	Hepatitis B (Child)	$50
	Hepatitis A (Child)	$54
	Diptheria/Tetanus/Pertussis, Hepatitis B (Adult), & Measles/Mumps/Rubella	$65
	IPV (Polio)	$80
	Hepatitis A (Adult)	$85
	Meningitis	$110
Other Services	Pregnancy Testing	$39
	Swimmer's Ear	$49
	Mono	$59
	Chlamydia (ages 16+)	$64
	Flu Diagnosis (ages 10-64)	$83